

(2) AGREEMENTS WITH PEER REVIEW ORGANIZATIONS.—Section 1876(i)(7)(A) (42 U.S.C. 1395mm(i)(7)(A)) is amended by striking "an agreement" and inserting "a written agreement".

(3) EFFECTIVE DATE.—The amendments made by this section shall apply with respect to contract years beginning on or after January 1, 1997.

to the anti-kickback penalties under subparagraph (A), the Secretary—

SEC. 216. ADDITIONAL EXCEPTION TO ANTI-KICKBACK PENALTIES FOR RISK-SHARING ARRANGEMENTS.

(a) IN GENERAL.—Section 1128B(b)(3) (42 U.S.C. 1320a-7b(b)(3)) is amended—

(4) by striking "and" at the end of subparagraph (D);

(5) by striking the period at the end of subparagraph (E) and inserting ": and"; and

(3) by adding at the end the following new subparagraph:

"(F) any remuneration between an organization and an individual or entity providing items or services, or a combination thereof, pursuant to a written agreement between the organization and the individual or entity if the organization is an eligible organization under section 1876 or if the written agreement, through a risk-sharing arrangement, places the individual or entity at substantial financial risk for the cost or utilization of the items or services, or a combination thereof, which the individual or entity is obligated to provide."

(h) NEGOTIATED RULEMAKING FOR RISK-SHARING EXCEPTION.—

(1) ESTABLISHMENT.—**IN GENERAL.**—The Secretary of Health and Human Services (in this subsection referred to as the "Secretary") shall establish, on an expedited basis and using a negotiated rulemaking process under subchapter 3 of chapter 5 of title 5, United States Code, standards relating to the exception for risk-sharing arrangements to the anti-kickback penalties described in section 1128B(b)(3)(F) of the Social Security Act, as added by subsection (a).

(7) FACTORS TO CONSIDER.—In establishing standards relating to the exception for risk-sharing arrangements

(i) shall consult with the Attorney General and representatives of the hospitals, physicians, and other health providers of the hospital, physician, and other health providers

actitioner, and health plan
communities, and other
interested parties; and

(8) (ii) shall take into account ~~the~~ the level of risk
appropriate to the size
and type of arrangement:

42 USC
1395mm
note.

(9) the frequency of
assessment and distribu-
tion of incentives;

(III) the level of capital
contribution; and

(IV) the extent to which
the risk-sharing
arrangement provides
incentives to control the cost
and quality of health care
services.

(2) PUBLICATION OF NOTICE. ~~In~~ In
carrying out the rule-
making process under this subsection,
the Secretary shall pub-
lish the notice provided for under
section 564(a) of title 5.

United States Code, by not later than 45
days after the date
of the enactment of this Act.

42 USC
1320a-
7b note.